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M. Wayne Western
Registered Patent Attorney
western@tnw.com

David W. Osborne
Registered Patent Attorney
osborne@tnw.com

March 17, 2005

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

TRANSMITTAL OF SUPPLEMENTAL
INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Re: U.S. Patent Application No. 10/700,838 filed 11/03/2003
Applicant: Fikstad et al
Title: **PHARMACEUTICAL COMPOSITIONS WITH SYNCHRONIZED
SOLUBILIZER RELEASE**
Group Art Unit: 1614
Attorney Docket No. 23625

Sir/Madam:

Transmitted herewith for filing and pursuant to 37 C.F.R. §§ 1.56 and 1.97 is a Supplemental Information Disclosure Statement. Enclosed also are the following designated documents, as required under 37 C.F.R. §§ 1.97 and 1.98:

- ☒ Form PTO-1449 list of 13 references submitted for consideration.
- ☐ Legible copies of the listed references or their relevant portions.
- ☒ Legible copies of the listed non-patent documents and foreign documents or their relevant portions are included.
- ☒ Copies of U.S. patents and/or publications are not included pursuant to the Official Gazette Notice, dated Aug. 5, 2003, waiving the requirement of 37 C.F.R. 1.98(a)(2)(i).
- ☐ All English translations of each non-English reference, if any, within the possession, custody, control or availability of anyone designated in 37 C.F.R. § 1.56(c) (see 37 C.F.R. § 1.98(c)).

www.tnw.com

8180 South 700 East • Suite 200 • Sandy, Utah 84070-0562 • f. 801.566.6633 • f. 801.566.0750 • patlaw@tnw.com | U.S. Mailing Address: P.O. Box 1219 • Sandy, Utah 84091-1219

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The following are included within the Information Disclosure Statement if applicable and as required under 37 C.F.R. § 1.98:

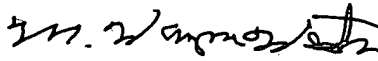
- ☐ Concise explanation of relevance of each reference not in English and unaccompanied by an English translation.
- ☐ Statement that certain listed references not enclosed are substantially cumulative of an enclosed reference.
- ☐ Statement that certain listed references not enclosed were previously cited by or submitted to the Office in prior application no. _____, filed on _____, which is relied upon for an earlier filing date under 35 U.S.C. § 120.

In order to secure consideration of the items designated above, one or more of the following, if required, is also enclosed:

- ☐ Statement under 37 C.F.R. § 1.97(e)(1) or (2).
- ☐ Check No. _____, which includes the amount of \$180.00 (amount in § 1.17(p)) constituting the submission fee set forth in 37 C.F.R. § 1.17(p).

In the event that 37 C.F.R. § 1.97(c) applies and the Examiner is not satisfied that the Statement meets the requirements of 37 C.F.R. § 1.97(e), or in any other event remediable by a fee, please credit any over payment or charge any additional fees to Deposit Account No. 20-0100 of the undersigned.

Respectfully submitted,



M. Wayne Western
Attorney for Applicant
Registration No. 22,788

THORPE NORTH & WESTERN, LLP
Customer No. 20,551
P.O. Box 1219
Sandy, Utah 84091-1219
Telephone: (801) 566-6633


MWW/DWO/jmw



IN THE UNITED STATES PATENT & TRADEMARKS OFFICE

ART UNIT: 1614

EXAMINER:

APPLICANT: Fikstad et al.

SERIAL NO.: 10/700,838

FILED: 11/03/2003

CONFRM. NO.: 5766

FOR: PHARMACEUTICAL COMPOSITIONS WITH
SYNCHRONIZED SOLUBILIZER RELEASE

**CERTIFICATE OF MAILING
UNDER 37 C.F.R. § 1.8**

DATE OF DEPOSIT: 3-17-05

I hereby certify that this paper or fee (along with any paper or fee referred to as being attached or enclosed) is being deposited with the United States Postal Service as first class mail with sufficient postage on the date indicated above and is addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Judy Wagner

**SUPPLEMENTAL INFORMATION DISCLOSURE
STATEMENT UNDER 37 C.F.R. § 1.97**

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir/Madam:

Please find, pursuant to 37 C.F.R. § 1.98(a)(1), the enclosed Form PTO-1449 which contains a list of all patents, publications, or other items that have come to the attention of one or more of the individuals designated in 37 C.F.R. § 1.56(c). Applicant respectfully submits that this Information Disclosure Statement is filed pursuant to:

☒ 37 C.F.R. § 1.97 (b)(1) or (3), within three months of the filing date of the application, or before a first office action on the merits, whichever occurs last;

☐ 37 C.F.R. § 1.97 (c), after a first office action on the merits, but before a Final Office Action or a Notice of Allowance, whichever occurs first, and is accompanied by either 1) a statement in accordance with 37 C.F.R. § 1.97(e), or 2) the fee set forth in § 1.17(p); or

☐ 37 C.F.R. § 1.97 (d), after a Final Office Action or Notice of Allowance, whichever occurs first, but on or before payment of the issue fee, and is accompanied by both 1) a statement in accordance with 37 C.F.R. § 1.97(e), and 2) the fee set forth in § 1.17(p).

While no representation is made that any of these references may be "prior art" within the meaning of that term in accordance with 35 U.S.C. §§ 102 or 103, the enclosed list of references is disclosed so as to comply with the duty of disclosure set forth in 37 C.F.R. § 1.56.

Moreover, while no representation is made that a specific search of office files or patent office records has been conducted or that no better art exists, the undersigned attorney of record believes that the references listed, together with any other references which may have been previously submitted or listed, are the closest to the claimed invention (taken in its entirety) of which the undersigned is presently

Supplemental Information Disclosure Statement

Application No. 10/700,838

Page 2

aware, and no art which is closer to the claimed invention (taken in its entirety) has been knowingly withheld.

☐ A legible copy of each listed U.S. Patent or publication (or relevant portion thereof) which was not previously submitted to, or cited by, the Patent Office is enclosed pursuant to 37 C.F.R. §§ 1.97 and 1.98.

☒ A legible copy of each of the listed non-patent literature and foreign documents or their relevant portions is enclosed.

☒ Copies of cited U.S. patents and/or publications are NOT enclosed pursuant to the Official Gazette Notice, dated Aug. 5, 2003, waiving the requirement of 37 C.F.R. § 1.98(a)(2)(i).

☐ Copies of the references listed in the accompanying Form PTO-1449 are NOT enclosed because, under 37 C.F.R. § 1.98(d), they were previously cited by or submitted to the Office in application number _____, which is relied upon for an earlier filing date under 35 U.S.C. § 120.

For all listed references that are not either in the English language, or accompanied by a translation into English, a concise explanation of relevance as required under 37 C.F.R. § 1.98(a)(3) is enclosed attached to each.

The Commissioner is hereby authorized to charge any additional fees associated with this communication or to credit any overpayment to Deposit Account No. 20-0100.

Dated this 17 day of March, 2005.

Respectfully submitted,



M. Wayne Western
Attorney for Applicant
Registration No. 22,788

THORPE NORTH & WESTERN, LLP
Customer No. 20,551
P.O. Box 1219
Sandy, Utah 84091-1219
Telephone: (801) 566-6633


MWW/DWO/jmw
Enclosure

EXAMINER INITIALS		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	A1	5,374,446	20-Dec-94	Ferenz et al.			
	A2	5,403,593	04-Apr-95	Royce			
	A3	6,221,395	24-Apr-01	Maggi et al.			
	A4	6,458,373	01-Oct-02	Lambert et al.			
	A5	6,569,463	27-May-03	Patel et al.			
	A6	6,623,755	23-Sep-03	Chen et al.			
	A7	6,630,134	07-Oct-03	Klein			

EXAMINER INITIALS	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	<u>TRANSLATION</u> YES NO
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	A8	Beatch, G.N. et al. Ventricular Fibrillation, an Uncontrolled Arrhythmia Seeking New Targets. Drug Development Research 55:45-52, 2002, page 48, para. 2, lines 6-16.
	A9	Julien, R.M. A Primer of Drug Action (Ninth Edition), 2001. p. 5-6.
	A10	The Merck Index. "Alpha Tocopherol". Monograph 09571. Merck & Co. 2001-2004. See Whole Document.
	A11	The Merck Index. "Carvedilol". Monograph 01888. Merck & Co. 2001-2004. See Whole Document.
	A12	The Merck Index. "Risperidone". Monograph 08316. Merck & Co. 2001-2004. See Whole Document
	A13	The Merck Index. "Ziprasidone". Monograph 10224. Merck & Co. 2001-2004. See Whole Document

DATE CONSIDERED

***EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication with applicant.